

II. REMARKS

A) Status

This preliminary amendment accompanies a CPA filed herewith. The amendments and remarks herein are responsive to the issues raised in the final Office Action mailed May 15, 2000 (Paper No. 16) in the parent of the instant CPA. Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "Version with markings to show changes made."

B) The Assignees of the Instant Application

In Paper No. 16, page 2, the Office requested that Applicants identify "the assignee of the instant application." Inventor CAMERON has assigned to the University of South Florida. This assignment is recorded at Reel 010476, Frame 0014. The assignee, if any, of the rights of inventor SELAWRY is not known. As noted in the Petition under 37 C.F.R. §1.47(a) filed June 3, 1997, Dr. Selawry has refused to sign a declaration for the subject application. Further, as noted in the Declaration of Denise Lade that accompanied the Petition under 37 C.F.R. §1.47(a) filed December 30, 1999, Dr. Selawry has also refused to sign an Assignment document. Thus, the undersigned Applicants' representative is unable to determine the assignee, if any, of Dr. Selawry's rights in the instant application.

C) Rejections Citing 35 U.S.C. §112

Claim 50 was rejected under §112, first paragraph, because the claim was believed by the Examiner to be broader than what was "originally disclosed at the time the application was filed." To expedite prosecution, and without intending to indicate agreement with the Examiner's position, Applicants have amended claim 50. As amended, claim 50 is directed to a method of treating Type I diabetes mellitus. Support for claim 50 is replete in the specification, for example, at page 3, lines 17-19 ("Type I diabetes is caused by an autoimmune reaction that causes complete destruction of beta cells), page 17, lines 15-19 ("A preferred embodiment of this invention is directed to a method of treating Type I and Type II diabetes mellitus by transplanting islet of Langerhans in conjunction with Sertoli cells into the renal subcapsular space"), and pages 21-51 (Examples).

Applicants submit that claim 50, as amended, is fully supported by the specification. Applicants respectfully request that this rejection be withdrawn.

D) Obviousness-Type Double Patenting

Claims 47-49 stand rejected under the judicially-created doctrine of "obviousness-type" double patenting in view of claims 1-6 of Patent No. 5,759,534. This rejection mooted by the cancellation without prejudice of claim 47-49.

Request for Interference (Renewed)

In view of the amendments to the claims, Applicants believe the only remaining rejections are statutory double patenting rejections. In response to the double patenting rejections, and pursuant to 37 C.F.R. § 1.607, Applicants renew their request that an interference be declared in order to settle an issue of inventorship of the claimed subject matter. Any double patenting rejections will be obviated by the outcome of any Interference.

Accordingly, as detailed below, Applicants renew previously made requests for a declaration of interference. Note that additional comments relating to amended claim 50 are found in paragraph 3, below.

1) Applicants renew the request that an interference be declared between the pending application and U.S. Patent No. 5,725,854 (also referred to as "the '854 patent").

Applicants propose the following Count:

A method of treating a disease that results from a deficiency of a biological factor in a mammal wherein said method comprises administering Sertoli cells and a therapeutically effective amount of cells that produce said biological factor to a mammal in need of such treatment, where said Sertoli cells are administered in an amount effective to create an immunologically privileged site.

The proposed Count corresponds to, at least, claim 1 and 2 of the '854 patent and claim 1 of pending application. This request was first made on October 1, 1998, within the period set by 35 U.S.C. § 135(b).

2) Applicants renew the request that an interference be declared between the pending application and U.S. Patent No. 5,759,534 (hereinafter "the '534 patent").

Applicants propose the following Count:

A pharmaceutical composition comprising Sertoli cells and a pharmaceutically acceptable carrier.

The proposed Count corresponds to, at least, claim 6 of the '534 patent and claim 46 of pending application. This request was first made on October 1, 1998, within the period set by 35 U.S.C. § 135(b).

3) Applicants renew the request that an interference be declared between the pending application and U.S. Patent No. 5,849,285 (also referred to as "the '285" patent). Although the claims are not identical, Claim 50 of the present application claims the same patentable invention as, at least, claim 1 of the '285 patent. The autoimmune disease recited in claim 50 (Type 1 diabetes mellitus) is a species of the genus "autoimmune disease" recited in claim 1 of the '285 patent. Accordingly, the (specific) invention of claim 50 anticipated the (generic) invention recited in claim 1 of the '285 patent.

Applicants propose the following Count:

A method of treating an autoimmune disease in a mammal wherein said method comprises transplanting into said mammal a therapeutically effective amount of isolated Sertoli cells to a transplant site in said mammal having said autoimmune disease, wherein said site is other than testes.

The proposed Count corresponds to, at least, claim 1-3 of the '285 patent and claim 50 of the pending application. The request that an interference be declared was first made on March 10, 1999 (Paper 12), within the period set by 35 U.S.C. § 135(b).

4) Applicants renew the request that an interference be declared the pending application and U.S. Patent No. 5,843,430 (also referred to as "the '430 patent").

Applicants propose the following Count:

A compartmentalized kit comprising a first container containing Sertoli cells and a second container containing cells that produce a biological factor that is absent or defective in a disease.

This proposed Count corresponds to, at least, claims 1 and 2 of the '430 patent and claims 47, 48, 51 and 52 of the pending application. This request was first made March 10, 1999 (Paper 12), within the period set by 35 U.S.C. § 135(b).

III. CONCLUSION

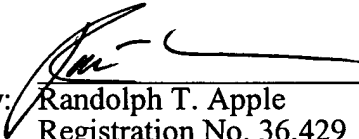
Applicants submit that the claimed subject matter meets the requirements for patentability under 35 USC and requests the Declaration of an Interference under 37 C.F.R. § 1.607 to settle an issue of inventorship of the claimed subject matter.

In the unlikely event that the fee transmittal is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 311772000321. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

In the event the Examiner wishes to discuss this application or anything pertaining thereto, the Examiner is invited to telephone Applicants' attorney at the telephone number listed below.

Respectfully submitted,

Dated: June 15, 2001

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